November 2009 Lab Accreditation Rule Workshop Summary

Comments & Questions/*Ecology Responses*

1. Revenues and expenses should be distinct from the general fund.
   Can we get the accreditation program out of the general fund?

Currently, fees paid for lab accreditation go directly into the state general fund. We have inquired about creating a separate fund, but the amount of fees collected for lab accreditation is too small to justify a new fund.

2. Third-party labs should pay full fees.
   The fee structure should be the same for out-of-state labs.
   Why don't third-party labs pay full fees?
   Does the 25% discount for third-party accreditation apply to the $300 minimum fee?
   For labs with both third-party and direct accreditation, does the 75% rate apply to both?
   We should consider National Environmental Laboratory Accreditation Program (NELAP) accreditation when calculating fees for labs with both direct and NELAP accreditation.

The new fee schedule we presented at the November 2009 workshops proposed increasing our fee for recognition of third-party accreditation from $345 to 75% of the full fee that we would normally charge to accredit a lab. The 25% discount from the full fee is intended to reflect our reduced work load for these labs, specifically the fact that we do not need to do on-site audits because these are done by the third-party accrediting authority. The 75% rate does not apply to direct accreditation.

3. The Pennsylvania fee structure allows charging by category of lab or by parameter.

Pennsylvania offers separate state and national (NELAP) accreditation. Within the state program, accreditation fees are based on category of parameters, for example, the state has one flat fee for inorganics in non-potable water. This approach could have the effect of penalizing smaller labs and giving an unfair advantage to the large commercial labs that can be accredited for many parameters in each category for the same fee.

4. Audit checklists are useful but we should be efficient about how we use them.

Don't go through the entire checklist during the audit if it was filled out in advance.

We agree and this is our current operating practice.

5. We should have a minimum fee and maximum fee for metals.
   We should charge for accreditation of a parameter in only one matrix, i.e. no additional fees for other matrices.
   Make it clear that the fee structure is for each matrix, not for all matrices.

Our proposed fee schedule is based on fee-for-service. The proposed fees now reflect the level of effort required to accredit a lab for the particular parameter(s) and method. We are proposing to eliminate maximum fees for most analytical categories because they are not consistent with charging fee-for-service and they provide an unfair price discount for larger labs.

We currently do not charge for the identical parameter (analyte and method) in a second matrix and we propose to continue that practice. For example, on a fee-for-service basis, it takes no more resources to accredit for alkalinity by SM 2320 B in non-potable water when we already accredit the lab for the same parameter in drinking water.

We will modify the language in the rule to clarify that the fee structure applies to each matrix, except as noted above.

6. Reduce the fee for mercury by cold vapor atomic absorption (CVAA) so it isn't $400 per analyte.

Our proposed fees would charge for metals by method instead of analyte. Most metals methods report multiple analytes. In the case of CVAA, only a single analytical result is produced – for mercury. However, CVAA methods use different technology and require roughly the same level of effort to accredit as other metals methods, so we propose charging full fee for CVAA.

7. Clarify method vs. technology – proposed fees are for method and technology.
   For example, 200.7 and 6010 are different methods but same technology.

The distinction relates to the level of effort required to accredit the lab for each parameter (analyte and method). The sample preparation procedures for water samples by Method 200.7

are different from those for solid samples by Method 6010. Different proficiency testing (PT) sample results must be reviewed and the quality control (QC) and details required in each of the procedures are different. So, while the technology is the same, accreditation for each of these methods requires sufficient effort to justify a separate fee for the additional service.

8. Labs in good standing should be audited less frequently.
   Use paper audits instead of on-site audits for good-performing labs.
   Use paper audits for all labs.
   Alternate paper audits and on-site audits every three years.
   What documentation would we ask for in a paper audit?

We are reducing the frequency of audits where we can due to a budget-related staff reduction. We are currently required to conduct on-site audits of drinking water labs every 3 years, and other environmental labs every 3 to 4 years. We are proposing to drop the 3 to 4 year audit requirement for non-drinking water labs, and would need to prioritize labs for on-site audits based on other criteria. One possible alternative would be to conduct paper audits by reviewing standard operating procedures, quality assurance manuals, and complete data packages to determine which labs are most in need of an on-site audit.

9. City and county labs should pay the same fee as commercial labs.
   Ecology's lab should pay for accreditation.
   Are state agency labs exempt from fees? This is an equity issue, a competitive advantage.
   State labs should pay accreditation fees.
   All labs should pay fees since they compete with commercial labs.

With very few exceptions, all accredited labs are subject to the same fee structure. However, we will consider these remarks further as part of rule development. We also plan to consult with the WA Department of Health and US Environmental Protection Agency regarding the future status and role of the two primacy drinking water reference labs.

10. Labs would like better communication with the state Department of Health on changes in drinking water program requirements.

We have forwarded this comment to the Office of Drinking Water at the Department of Health.

11. What if some labs drop Washington State accreditation because of the fee increase?
    Do revenue assumptions consider possible loss of out-of-state labs?

This is difficult to predict. Our fee proposal anticipates that some labs may drop out of the program.

12. Review our business practices for recognition of NELAP accreditation.

We have a standard operating procedure, and for consistency we will compare our practices for third-party recognition of NELAP accreditation with those where we provide accreditation to labs directly.

13. Would a cap on microbiology tests make sense?

We agree that different levels of effort may be required to accredit for various types of micro tests. We will evaluate this further and try to arrive at a fair average fee for microbiology tests.

14. Reduce proficiency testing (PT) requirements to one/year because it is a significant cost for large labs.
    Reduce or waive PT requirements for labs with good performance.

PT results are our only on-going indicator of lab performance. With our audit frequency being reduced for most labs, PT results will become even more important since the performance of a lab is not necessarily constant over time.

15. We should encourage permit writers to remove obsolete methods from permits.

We do try to communicate regularly with our Water Quality Program permit writers. We will forward this comment to them.

16. Why do our proposed fees increase more than other state's fees based on size of labs?

The fee-for-service approach is more equitable than our current fee structure and shifts more of the necessary fee increase to the larger labs based on the level of effort required to oversee their accreditation.

17. Would prefer small incremental fee increases rather than one large one.
    It is easier for labs to budget for small annual fee increases.
    Post to web site how fees are not keeping up with the Consumer Price Index.

Our current regulation allows for annual incremental fee increases to keep up with inflation. However, Initiative 960 amended RCW 43.135.055 so that fee increases now require legislative approval. The 2009 legislature did give Ecology the authority to raise accreditation fees to cover program costs during the current biennium but did not authorize incremental increases beyond this biennium.

18. Will the small business economic impact statement cover government labs?

No, government labs are not included in the SBEIS. The SBEIS applies only to private business entities, including but not limited to sole proprietorships, partnerships, and corporations. Impacts on government labs will, however, be included in the Cost-Benefit Analysis and Least Burdensome Alternative Analysis.

19. On-site audits find the same deficiencies time after time – consider reducing audit frequencies.

Those deficiencies need to be corrected. The solution is to follow up to ensure compliance, not to reduce audit frequency.

20. Please notify labs of changes in accreditation requirements before we audit them.

The audit system in our new data base will use NELAP-type checklists to ensure more consistent application of accreditation requirements among our auditors.

21. Consider significant changes in laboratory staff in audit decisions.

We do consider specific circumstances at a laboratory in our accreditation decisions. However, these cannot be reasons for failure to meet accreditation requirements.

22. Post an EXCEL spreadsheet on our web site so that labs can compute their fees.

After our revised rule has been adopted and we have a final fee schedule, we plan to post a fee calculator on the lab accreditation web site.

23. Clients' options are limited if labs can't afford to be accredited for less-frequently requested parameters.

Our proposed fees reflect the level of effort required to accredit laboratories for the various parameters they request. Laboratories will, in turn, have to charge clients according their cost of maintaining the capability to perform required tests.

24. In your workshop presentation, you compare fees in different states based on lab size. What is the criterion for lab size?

For the presentation, we based lab size on the number of accredited parameters, which is roughly proportional to current accreditation fees. Small labs had less than 10 parameters, all in non-potable water. Medium-sized labs had a total of about 50 parameters distributed in drinking water, non-potable water, and solid and chemical materials. Large labs had over 200 parameters distributed in all three matrices.

25. Some labs may need audits to maintain accreditation in other states.

If a lab needs an audit by our staff to maintain their accreditation in another program, we will arrange to meet that requirement.

26. Why did the wastewater labs not have to be accredited until 1994?

Washington State regulations governing wastewater discharge required permitted dischargers to begin to use accredited labs in the early 1990s. This requirement was phased in over two years to allow wastewater labs to either become accredited or to contract with another accredited lab for analytical services.

27. Are there good PT samples for microbiology testing?

Yes.

28. Electronic renewals would be nice.

Our new data base gives us that capability, and we hope to move in that direction soon.

29. When we audit a lab for drinking water parameters, would we also audit for those same parameters in other matrices?

We include all matrices in the audit.

30. Try renewals every two years.

Our current regulation allows variable renewal periods up to two years on an individual basis "for cause". This was to help spread the schedule of renewals throughout the year.

Renewal is an opportunity for us to review the accreditation status of the lab and we believe that should occur at least annually.

31. The proposed fees are harder on small labs with less revenue. Is there a way to help small labs stay in business?

The proposed fees more closely reflect the level of effort required to accredit laboratories and therefore are more equitable for all labs.

32. The quality assurance officer of one of our large commercial laboratories could not attend the workshops but sent a suggestion that Ecology become a NELAP accrediting authority.

Some of the requirements for NEALAP accreditation, such as audits every two years, would add significantly to the workload of the laboratory accreditation program, which would require adding more staff and thus raising fees further.